IN THE SUPREME COURT OF THE UNITED STATES

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LABORATORY CORPORATION :

OF AMERICA HOLDINGS, DBA :

LABCORP, :

Petitioner :

V. : No. 04-607

METABOLITE LABORATORIES :

INC., ET AL. :

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Washington, D.C.

Tuesday, March 21, 2006

The above-entitled matter came on for oral argument before the Supreme Court of the United States at 11:12 a.m.

APPEARANCES:

JONATHAN S. FRANKLIN, ESQ., Washington, D.C., on behalf of the Petitioner.

THOMAS G. HUNGAR, ESQ., Deputy Solicitor General, United States Department of Justice, Washington, D.C., as amicus curiae, supporting the Petitioner.

MIGUEL A. ESTRADA, ESQ., Washington, D.C., on behalf of the Respondents.

C O N T E N T S

P R O C E E D I N G S

(11:12 a.m.)

JUSTICE STEVENS: Mr. Franklin, whenever you're ready, you may proceed.

ORAL ARGUMENT OF JONATHAN S. FRANKLIN

ON BEHALF OF THE PETITIONER

MR. FRANKLIN: Justice Stevens, and may it please the court, the patent claim at issue in this case was held to be infringed whenever any doctor looks at a homocysteine test result and reflexively thinks about a basic natural correlation. The result has been multimillion dollar damages and an injunction prohibiting a testing company from conducting important homocysteine tests by any method and for any reason whatsoever.

As broadly construed by the Federal Circuit, this claim is invalid as a matter of law for two closely related reasons. It contravenes both of this court's settled proscription against effectively patenting laws of nature or natural phenomena as well as the requirement that a patent must fully and clearly describe, disclose and enable an actual invention and must not sweep so far as to encompass more than what was actually invented.

JUSTICE KENNEDY: Is that second point -- is that second point definiteness?

MR. FRANKLIN: The second point is

definiteness, it's enablement.

JUSTICE KENNEDY: Does definiteness describe this second aspect that you've just --

MR. FRANKLIN: It describes part of it, Your Honor.

JUSTICE KENNEDY: Just part of it.

MR. FRANKLIN: There is definiteness, there is enablement, there is written description. We think all of those are contravened here.

JUSTICE SCALIA: Let's examine them. What if it definitely goes so far as to allow no other use of this natural law that it's discovered? It definitely goes that far, isn't definiteness fully satisfied?

MR. FRANKLIN: I think not, Your Honor, because --

JUSTICE SCALIA: No?

MR. FRANKLIN: -- definiteness would still require that you distinctly claim an invention here and that's one of the things that's absent in this case. But even moving beyond that, Your Honor --

JUSTICE KENNEDY: It's indefinite because we don't know where our thoughts will take us? Suppose there a patent which requires looking at the clouds in the sky for 10 minutes. I mean, that's maybe absurd, but it's certainly definite.

MR. FRANKLIN: Well, Your Honor, if it is definite, then it is certainly not enabling of an actual invention. And here the Morse case, which we have cited in our briefs, comes into play. In that case, the court held that Samuel Morse was entitled to patent his innovative telegraph but he couldn't go further to effectively patent the law of nature or natural phenomenon associated with it and thereby monopolize all manner of devices and processes that he did not invent and did not enable or describe.

JUSTICE GINSBURG: But wasn't the issue there what is patentable? I mean this case in the district court was under this definiteness idea, 112. 101 deals with what's patentable. And it seems to me that you, this case was presented as a definiteness case.

MR. FRANKLIN: But it was not just definiteness, Your Honor. It was Section 112. But let me get to the Morse case because as we have explained in our reply brief and, in fact, in our opening brief, the Morse case was in fact decided under what is now Section 112. The Court cited and quoted the relevant statute which has not changed in any material respect today. The Court made clear that the problem in that case, at page 120 of the opinion, was that Morse claims what he has not described in the manner required by law.

And what we have here is the same situation.

We have these patentees who are indisputably entitled to patent their innovative method for measuring homocysteine. And LabCorp continues to use that method sometimes and we pay royalties whenever we use that method. But what they couldn't do is what Samuel Morse tried to do and push the envelope, and try to effectively patent the natural phenomenon associated with all homocysteine tests and thereby gain a monopoly over just not the one that they invented, not just those that are in the prior art, which itself would be impermissible, but even yet to be invented assays.

And here is the nub of this case. LabCorp has sought to use but has been penalized for using and is prevented from using a more efficient and cost-effective method for assaying homocysteine than the one that these patentees invented. The method that LabCorp seeks to use, which is the Abbott method, reduces the processing time for homocysteine tests down from what was up to 18 hours under the patentee's method down to a manner of minutes.

JUSTICE GINSBURG: Is the Abbott test -- that's patented and you're paying royalties for that?

MR. FRANKLIN: Actually, I don't know, Your Honor. And, I just don't know whether it's patented but it is certainly not covered by their claims 1 through 12, which have never been -- well, the district court found that those

claims didn't apply here, and that's not an issue.

The Abbott method is different. It's an immunoassay. It is not the same kind of mass spectometry gas chromatograph method that they have described. It's much more efficient, it's much more cost-effective and the reason obviously that LabCorp wants to use that method is to more effectively serve patients and their doctors and to meet the burgeoning demand for homocysteine tests. But because these patentees have effectively claimed the patent on the natural correlation that's associated with all homocysteine tests, they have prevented LabCorp from using what the patent laws would seek to encourage, that is, a more cost-effective, innovative, different method, the kind of thing -- exactly the kind of thing that the Court was concerned about in Morse.

JUSTICE KENNEDY: The opinion of the Court of Appeals for the Federal Circuit in the appendix begins discussion of claim 13 about page 16a. Are there some, one or two sentences there or a paragraph that you can tell me is completely wrong?

MR. FRANKLIN: In the Federal Circuit's --

JUSTICE KENNEDY: Yes. You're asking us to reverse this court of appeals decision and I'm looking, and particularly with reference to claim 13, the one we're talking about, I assume, and I'm looking through pages, say,

16 and 21 to find something that's absolutely wrong.

MR. FRANKLIN: Well, I think what --

JUSTICE KENNEDY: You want me to tell the court of appeals, well, you can't do this. But where is it wrong?

MR. FRANKLIN: I think where it's wrong, Your Honor, is that it proceeds from an assumption that is wrong in itself and that is --

JUSTICE KENNEDY: So you can't point me to any particular sentence that would say that's absolutely wrong?

MR. FRANKLIN: I think that the argument in -- the Federal Circuit's decision is wrong in its enablement discussion, it's wrong in its written description discussion. I mean, just to take one, the written description posits that this is a valid written description because the inventors, as the Federal Circuit says in its opinion, possessed the correlating step. And I think what's wrong about that, Your Honor, is that nobody can possess the correlation. And that's the nub of this case.

JUSTICE KENNEDY: And where does it say this?

MR. FRANKLIN: I'm sorry, that is at page -- I believe it's at 17 of the appendix. Let me just make sure I've got the right -- that was where the court talks about --

JUSTICE KENNEDY: You see my point? I'm not sure what it is you want me to say went wrong, other than

the fact that this patent is, should never have been granted to begin with but that wasn't raised.

MR. FRANKLIN: Well, I think it was raised, Your Honor. The validity issue was raised in the district court, it was raised on appeal. The district court had construed the patent as requiring -- and part of the district court's claim construction addressed the issue as to whether or not one could patent a law of nature or effectively patent a scientific idea. The district court said this patent must require something more, and that is at joint appendix page 60. It must require something more than simple existence of the relationship between homocysteine and vitamin deficiencies. And one of the places that the Federal Circuit did get it wrong, Your Honor, was in abandoning that limitation that the district court had imposed on the patent.

JUSTICE BREYER: I guess that --

JUSTICE SOUTER: But you're arguing now, as I understand it, that the reason you win on definiteness is that it sweeps in even as yet uninvented processes.

MR. FRANKLIN: Yes.

JUSTICE SOUTER: And it does so by means, in effect, of erecting this umbrella of a natural fact which is intended to cover every process that might be relevant to establishing that natural fact.

MR. FRANKLIN: Yes.

JUSTICE SOUTER: So that you're saying we cannot -- no court can decide definiteness in this situation without hitting the patentable issue.

MR. FRANKLIN: Absolutely, Your Honor. That's exactly what we're arguing. And that's where the Federal Circuit got it wrong. And we did in fact urge the Court --

JUSTICE BREYER: But you told the -- you said, judge, if you in fact hold that this claim 13 satisfies Section 112 and is sufficiently precise and specific and concise, if you hold that, then the claim would violate Morse?

MR. FRANKLIN: Yes.

JUSTICE BREYER: And you argued that specifically? And so your problem -- I guess that you said that. I mean, you quote it in your supplementary brief on page 6.

MR. FRANKLIN: We did say that. Yes.

JUSTICE BREYER: And it's the language.

MR. FRANKLIN: Yes.

JUSTICE BREYER: That's what it said. It didn't say Morse. It said Diehr.

MR. FRANKLIN: Diehr, which --

JUSTICE BREYER: Dier incorporates Morse.

MR. FRANKLIN: Yes.

JUSTICE BREYER: As I understand.

MR. FRANKLIN: Yes.

JUSTICE BREYER: So your complaint about the paragraph on 117a is that it did not deal with that argument.

MR. FRANKLIN: Yes.

JUSTICE BREYER: But I imagine they'll say that simply mentioning it in an oral argument is not enough to get us to think seriously about it.

MR. FRANKLIN: Well, it was in the brief, Your Honor, and I think that it was also in, with the premise of everything that we argued, because the district court had already -- and again, I point the Court to joint appendix page 60. The district court had already held that it had to mean -- the patent had to mean something more than the simple relationship, the simple existence of the relationship between elevated homocysteine and vitamin deficiencies. And the premise of the entire Federal Circuit argument and, in fact, to the arguments below was that we don't know what that anything is, because the patent doesn't tell you.

The Federal Circuit blew past that, Your Honor, and what the Federal Circuit said, which makes the issue front and center now, is the Federal Circuit said, and this is at 18a. "The correlating step is a simple conclusion

that a cobalamin/folate deficiency exists vel non based on the assaying step."

And what that means is now, as a result of the Federal Circuit's decision, unlike the district court's decision, we now know that every homocysteine test automatically infringes because every doctor will reflexively look at it and think about the phenomenon associated with it.

JUSTICE GINSBURG: You said both the district court and the court of appeals but you don't think the district court got it right, either. You said the district court required something more.

MR. FRANKLIN: Yes.

JUSTICE GINSBURG: What was the something more and why wasn't that adequate?

MR. FRANKLIN: We don't know and that's why it wasn't adequate. That's why we had always argued under indefiniteness and under enablement, under the written description. We had no idea. The patent doesn't tell you. We suggested one way. That wasn't -- the Federal Circuit didn't agree with us. The problem with the district court's -- we agreed with the district court's claim construction. That far, we did. But then there was nothing more even adduced at trial, and this was the argument we consistently made. The Federal Circuit then abandoned what

the district court did and then we here have at front and center --

JUSTICE GINSBURG: What the district court did is it got, it tried this case and it got a rather large jury verdict.

MR. FRANKLIN: Yes.

JUSTICE GINSBURG: And I don't understand how you're setting off the district court from the court of appeals when the court of appeals, whatever it said, it affirmed the judgment of the district court.

MR. FRANKLIN: It did, but the claim construction is the part of what I'm talking about. At page 60, I'll just read what the district court said. "Correlating is a verb and must mean more than the simple existence of a relationship between a high level homocysteine and deficiency in cobalamin or folate."

The Federal Circuit's opinion is contrary to that, Your Honor, and that's where this whole issue gets put front and center now. And what we have here under the Federal Circuit's extraordinarily broad construction is we have nothing more than the reflexive mental recognition of a natural correlation preceded by the inherent and generic step of somehow ascertaining the input for that correlation.

JUSTICE STEVENS: I could see how that broad interpretation would raise perhaps for the -- clearly raise

for the first time the Section 101 issue. But, so that should have been clear to you by the time the court of appeals decision came out, right? But did you, in your petition here, rely on 101?

MR. FRANKLIN: Well, we relied, Your Honor, on all of, many, many cases interpreting that provision and others under the law of nature --

JUSTICE STEVENS: You never mentioned 101, though, did you?

MR. FRANKLIN: We didn't but just as an example, Your Honor. The court's invitation or, to the solicitor general didn't mention 101, but everybody knew what the court was talking about. And let me just -- the petition couldn't have raised -- the petition squarely raised the issue. On page 18, we cited Diamond versus Diehr, Benson, Funk Brothers, Mackay Radio and the Le Roy case from 1852. On page 26, we cited, quoted, relied on Funk Brothers and Mackay Radio again. Page 27 refers back to the authorities at page 18 of the petition. Page 28 states that under the Federal Circuit's holding, anyone who claims to be the first to discover scientific correlation could patent it simply by drafting the vague test plus correlate claim.

This issue was presented in the petition. It is within the question presented. And, Your Honor, I think

that the issue is easy to resolve given the Federal Circuit's broad construction. Under that construction, again, there is nothing more than the recognition of the natural phenomenon preceded by what is the inherent step in any natural correlation of ascertaining the input. And as we have said without contradiction in the opening brief, if this patent is valid, then anyone can gain a patent over a scientific correlation by doing this kind of artful drafting. Einstein could have patented E=MC2 which this Court has stated on more than one occasion could not be patented simply by doing a test plus correlate.

To take another hypothetical that was stated in the opening brief without contradiction, if I discover tomorrow a new correlation between having a certain kind of blood type and a medical condition that heretofore people do not know about, I could run down to the Patent Office, patent that correlation and the effect of that would be to monopolize all blood typing, no matter whether it's done through methods in the prior art or methods yet to be developed.

JUSTICE ALITO: Is it true as the respondents argue that a holding in your favor would call into question thousands of patents?

MR. FRANKLIN: Well, they don't mention all -- the number but I don't think it would call into question a

huge swath of patents. It would call into question patents that are like this one, obviously, things that are simply test plus correlate.

JUSTICE ALITO: And do you have any idea how many there are of those?

MR. FRANKLIN: No. You would have to do an exhaustive search. There are some and I believe that some of the ones that the respondents cite, some of the claims -- and let's distinguish between patents and claims here, because it might invalidate some claims in some patents, which is not unusual because patent drafters often push the envelope. The patentors in this case, they have indisputably unchallenged and valid patent claims for a method of measuring homocysteine, but they went further in claim 13. And to the extent there are other patents that might have those kind of claims, yes. But to the extent we're talking about the broader swath of patents dealing with things like genes, no.

JUSTICE KENNEDY: If there is some likelihood or possibility of this that we should assess, it seems to me that it's imprudent for us to discuss it here when it hasn't been discussed in the court of appeals.

MR. FRANKLIN: I think, well, it was, again, it was pressed in the court of appeals. But again, what we're talking about is deciding this case on its facts and

obviously to the extent there are other patents that are just like this one, and the court has addressed this in the context of Flook and Diehr and has distinguished between those patents which facially looked rather similar but the court was able to draw the distinctions. The Federal Circuit can draw the distinctions.

But if it is a patent that is simply like this one, which claims nothing more than a natural correlation preceded by the inherent step of ascertaining the input, no court, to my knowledge, has ever upheld such a patent before this case.

JUSTICE KENNEDY: You're urging on us something like plain error, is about what you're telling us.

MR. FRANKLIN: No, I think that we're urging the Court to examine the case that it has before it, look at the patent and we're not asking the Court to go further than this patent. Look at this patent, look at the Federal Circuit's construction and that's something that we will take as a given for purposes of today's proceeding.

JUSTICE STEVENS: When you say this patent, you really mean just claim 13, don't you?

MR. FRANKLIN: I'm -- excuse me, Justice. And again, I wanted, as I was saying to Justice Alito, you do need to distinguish between patents and claims. And claim 13 is the only claim that's been asserted here. It's the

only claim that's being challenged. And let me just --

JUSTICE SCALIA: Why shouldn't we do what the Solicitor General proposed, that is, since we don't know for sure, at least I don't know for sure, I'm not enough of a scientist, whether in fact the Section 112 determination, as made by the federal court, excludes all other possible use of this natural phenomenon.

Since I don't know that for sure, why shouldn't I tell the Federal Circuit, you know, your definition of correlate raises this issue and you should resolve whether it is true that there is no other possible usefulness for this, no substantial usefulness?

MR. FRANKLIN: Quite simply, Your Honor, it's because the Court doesn't need to reach that issue and didn't need to reach it in any of its prior cases save one and that's the Benson case where that issue came up really in one sentence of the opinion. In the Morse case, in the Funk Brothers case, in the Flook case, all of those patents had -- were limited to a particular use.

Just take Morse's patent which was limited to just conveying information at a distance through electromagnetism. That was actually one very small sliver of what you can do with electromagnetism. It's that, very, very small. And the court said, no, it doesn't matter. Where what you have is effectively the patent on the

correlation, it doesn't matter whether you can limit it to one use or many uses. So if the court -- so I don't think the Court needs to get into that. In Diehr, the Court made that explicit that a field of use -- limiting a patent to a field of use is not going to save that patent from invalidity.

Now, if the Court does examine the issue, it ought to do it the way it did it in Benson just by looking at the broad sweep here. And how I would use it, Your Honor, would be to say that in addition to all of the other problems that this patent, as construed by the Federal Circuit, has, it also has an extraordinarily broad pre-emptive sweep. It applies to any homocysteine test, no matter how it's done, no matter what reason it's done, no matter if it's in the prior art, no matter if I invent it tomorrow.

It applies to any act of even looking at the test. And here it's not just doctors. If anyone in the audience today learns about this correlation because of this argument, if they're listening carefully, and then they go to their doctor and ask for a test, they will, number one, be inducing infringement; number two, if they look at the test result, now being armed with what we have given them, which is the scientific knowledge that the correlation exists, they will infringe. And there was testimony in

trial to that effect.

So I don't think the Court needs to get into the inquiry. and I don't think the Patent Office really wants to get into that inquiry either, to have to look at each patent application to determine not just based on what's in it whether it's valid but whether there are other uses not even invented yet that might not be covered. That's not, I submit, what the Patent Office would like to do.

If I might reserve the remainder of my time.

JUSTICE STEVENS: You may, Mr. Franklin. I think Mr. Hungar is next. Mr. Estrada.

MR. ESTRADA: Oh, sorry.

JUSTICE STEVENS: You're too hungry, Mr. Estrada. Mr. Hungar?

ORAL ARGUMENT OF THOMAS G. HUNGAR

ON BEHALF OF THE UNITED STATES

DEPARTMENT OF JUSTICE AS AMICUS CURIAE

MR. HUNGAR: Thank you, Justice Stevens, and may it please the Court. Claim 13 satisfies the written description, enablement and definiteness requirements of Section 112 of the patent act. The patent specification sets forth the scope and nature of the claimed invention in terms readily understandable by a person of ordinary skill in the art and it enables such persons to practice the

claimed invention.

JUSTICE KENNEDY: So you agree or you submit that you can have a definite description of something that's unpatentable because it's too broad?

MR. HUNGAR: Well, that obviously assumes the conclusion, Your Honor. But with respect to the definiteness requirement, the challenge seems to be that because the first step of claim 13 is not limited to a particular type of assay but instead claims all assays, that that somehow renders it indefinite, and that argument is simply incorrect as this Court has recognized for over a hundred years.

In the Cochrane against Deener case, for example, the Court addressed that question where a process claim was not limited to a particular method of performing a particular step of the process, and the Court said, "A process may be patentable irrespective of the particular form of the instrumentalities used." And the Court reiterated that principle in the Diehr case.

JUSTICE KENNEDY: But, but, but -- well, let's assume that there is a claim that includes something that should not be patentable, because it's too broad or it involves the scientific phenomena, the mechanics of the universe. Can a patent still be definite if it includes that sort of unpatentable claim?

MR. HUNGAR: It can be. It might or might not be depending on the circumstances. The Morse case is an example where it was both indefinite and invalid because trying to claim a principle of nature, in effect. But by the same token you can easily have, and in fact you have here, a claim where it's definite in that persons of ordinary skill in the art understand the scope of the claims. They know what is and is not within the scope of the patent, which is, in this case, a question entirely separate from the question whether, as construed by the Court and as understood by the person of ordinary skill in the art, it's valid, under section 101, that is, under the scope of patentable subject matter.

JUSTICE STEVENS: What do you think about its validity under 101?

MR. HUNGAR: Your Honor, as we suggested in our brief, we don't think that that question is properly before the Court but that --

JUSTICE STEVENS: Excuse me. But I didn't ask you what you said in your brief.

MR. HUNGAR: Yes, Your Honor. But that if the Court were to reach that question, we think that while it's unclear because the issue wasn't litigated, there appears to be prima facie evidence of invalidity under Benson, this court's decision in Benson, because, given what we currently

know, it appears that the claim as construed by the court of appeals preempts all substantial practical applications of the correlation. But because that issue wasn't litigated below, if the Court were to reach it, it should remand --

JUSTICE STEVENS: The patent -- talking about step 1, you can use any assay method you want. It doesn't have to be patented. But the correlation, step 2, that any time you ask a doctor to tell us what you think the results of the test mean, that that's an infringement?

MR. HUNGAR: That's how the court of appeals construed it, yes, Your Honor. I'm sorry. Is that --

JUSTICE STEVENS: And is it possible that that cab be patentable, in your view?

MR. HUNGAR: Well, again, Your Honor, we --

JUSTICE STEVENS: If you just go to the doctor and ask for advice and he says, yes, I've looked at the results; you've got a vitamin B deficiency or whatever it is --

MR. HUNGAR: As we indicated --

JUSTICE STEVENS: -- he's committed infringement under this patent as I understand it.

MR. HUNGAR: As we indicated in our brief, we think that raises a potentially serious pre-emption problem and it also raises the anticipation problem, that is, the section 102 argument which is not before the Court but if it

were litigated --

JUSTICE STEVENS: It would raise the -- just do you think that that patent is valid? That's what I'm trying to ask you.

MR. HUNGAR: Well, we think it has validity problems under section 102 and also under the pre-emption, -- potentially under the pre-emption doctrine. We haven't addressed the other issues that petitioner seeks to put before the Court involving Diehr and Flook, both because -- well, actually for four reasons.

First of all, it wasn't blest or passed upon below, it wasn't -- it's not fairly included within the question presented, which construed at its most broad, broadly, includes only the monopolization issue --

JUSTICE STEVENS: I know all that. I'm just really interested in your view of the patent. That's what I'm trying to get to.

MR. HUNGAR: Yes, Your Honor. And as I've said, we've identified two areas in which we think there are potentially problems if they were in front of the Court.

JUSTICE STEVENS: Do you think there is a 101 problem too?

MR. HUNGAR: The preemption issue is a 101 problem, Your Honor. We haven't addressed -- as I said, we have not taken a position on the broader Section 101 issues

and we would urge the Court not to do so as well, in a case in which it wasn't presented below, the Court doesn't have the benefit of the lower court's assessment of that question. And given that that question implicates substantial reliance interests and --

JUSTICE STEVENS: So we do have a fairly long discussion by the lower court on the infringement issue. In order to find infringement, they had to construe correlation.

MR. HUNGAR: Yes, Your Honor.

JUSTICE STEVENS: Yeah.

MR. HUNGAR: But the Court didn't grant certiorari on that question. Yes.

JUSTICE BREYER: I didn't understand the definiteness doctrine. I mean, all these things in 1854 I guess weren't so clear. But I think the precise claim in Samuel Morse's case was the use of the motive power of the electric current for making or printing intelligible characters. That sounds absolutely definite. Anyone can understand it.

I thought the problem there was that although anyone can understand it, you can't claim something as broad as that. You must intend to claim something narrower. And insofar as it's narrower, it isn't precise. So insofar as it's broad, it's too broad, but definite. And insofar as

it's narrow, it's not there, but indefinite. Okay?

Precisely the claim that they raised before the Federal Circuit and precisely the claim -- with appropriate citations, and precisely the claim in respect to which the Federal Circuit said nothing.

MR. HUNGAR: Your Honor, I may have misspoken before but I think it's probably most accurate to read the Morse case as dealing with a written specification problem, that is, the specification in claim 8, the one Your Honor is referring to, didn't tell anything about the method by which the principle of nature, electromagnetism, would be used. All it did is describe a result, and it purported to claim any, any method involving any number of steps that any inventor might ever invent in the future, even if those steps had nothing to do with -- if there was not a single overlapping step between that new process and Morse's process.

JUSTICE BREYER: Yes, yes, yes, yes. And we here apply the correlation to any homocysteine test, anyone here, anyone in the future, anyone that any mind might impend. What's the difference?

MR. HUNGAR: Well, the difference is between claiming a -- claiming all methods of achieving a particular result and claiming one process for achieving that particular result and then as one claiming any means of

doing one particular step.

JUSTICE BREYER: I apply electricity to all methods of putting down letters with electricity. I apply the correlation to all methods of creating a homocysteine test.

MR. HUNGAR: Well, again, Your Honor, if it is true that all methods of employing the assay -- excuse me, all methods of employing the correlation are preempted by this patent claim, then it would be invalid under section 101. But to the extent the argument is an attempt to go beyond that issue, we submit Morse doesn't support it and indeed this Court's decision's in --

JUSTICE BREYER: Oh, no, I'm not talking about going beyond it. I just thought that line between definiteness and 101, 112, 101 is not quite so clear as I would have thought, because it sounds to me relying on the 1854 case of Samuel F. B. Morse, they're making the same kind of argument and, indeed, you translated Morse as a definiteness 112 argument, and yet it seemed to me that's the kind of argument they're making.

MR. HUNGAR: Yes, Your Honor. And I think it is more properly understood as a specification problem because, as you say, anyone can understand the scope of that claim. It's just that it was not sufficiently described because he was purporting to claim any process even if it

had nothing to do with the process he had invented, and that's not what's happening here. They claim a particular step, that is, do an assay, as opposed to some other method, and they claim any method of doing that assay within step 1 of the overall claim but they aren't saying -- first sense of the analogy would be if they had claimed we've just devised one particular method of determining whether someone has a vitamin deficiency and we therefore claim all other methods of determining whether someone has a vitamin deficiency.

JUSTICE SOUTER: Okay, I think you've hit what is the problem for us. When you use the word assay, you assume that that is excluding certain processes. And that's not clear to me. Would you explain that in greater detail?

MR. HUNGAR: Well, again, we don't know --

JUSTICE SOUTER: I thought an assay was in effect synonymous with any process that gets the relevant data and you're using it in a more -- I think, in answering Justice Breyer's question, you were using it in a narrower sense.

MR. HUNGAR: Well, I think that, as understood by a person having ordinary skill in the art, we -- it may be. We don't know because the issue wasn't litigated.

JUSTICE SOUTER: But I thought that was the point of your argument, that there are assays and then there

are other methods. Did I misunderstand you?

MR. HUNGAR: Well, no. Certainly it's conceivable that there are other methods and indeed the patent claim -- the patent specification refers to -- or suggests the possibility of assaying tissue as opposed to fluid. The claim is limited to fluid.

I thank the Court.

JUSTICE STEVENS: Mr. Estrada, it's your turn now.

ORAL ARGUMENT OF MIGUEL A. ESTRADA

ON BEHALF OF THE ON RESPONDENTS

MR. ESTRADA: Thank you, Justice Stevens. Thank you, Justice Stevens, and may it please the Court.

This was a hard fought jury trial in which the jury rejected everything LabCorp had to sell. That judgment should be affirmed for three reasons.

The first is LabCorp never asked the trial judge or the Federal Circuit to declare this patent invalid under Section 101, which is an affirmative defense they had to plead in the answer and prove by clear and convincing evidence.

Second, they're simply wrong on the merits of the 101 case under this Court's cases.

And third, you can search their brief in vain for a workable test for patentable subject matter that would

invalidate this patent and not wreak complete havoc to the patent world by calling into question numerous diagnostic tests in medicine and otherwise, pharmaceuticals and other inventions.

Let me deal briefly with the waiver question because we don't get a sur-reply brief and there is a lot in the reply brief that I wish I could deal with at length. But I think I will say that it is a collection of cropped quotes and very inventive characterizations of the record. I will give you just two examples.

At the bottom of page 9, they're trying to get out of their Unitherm problem, never having this raised in the answer or in the rule 50. And the footnote at the bottom of the page discusses the rule 50 and states or at least suggests that this argument in terms was raised before the trial court, concluding with the sentence, "Respondents themselves understood LabCorp to have thereby presented subject matter patentability." They cite to our brief on JMOL.

I have that here. This is what we said. "The quick answer to LabCorp's mental steps theme is that LabCorp never pled it in the defense. LabCorp. pled invalidity on the basis of 102, 103, 112 on the grounds that the patent was anticipated, obvious, indefinite, non-enabled and procured by inequitable conduct. But the so-called mental

steps doctrine goes instead to the question whether patent covers statutory subject matter. That is governed exclusively by section 1, 101. LabCorp has never mentioned that section and has never pled the patent is invalid for covering non-statutory matter even, in its present JMOL motion.

Footnote: LabCorp failed to assert invalidity on the basis of non-statutory subject matter in any of its five answers or counterclaims or in any of its interrogatory responses. None of its experts, including its patent law expert, made any such assertion in any reports or testimony. That gets translated in the reply brief as we understood this issue was in front of the courts.

Now, we made that point in our papers. There was no response saying, no, wait, district judge, this isn't the case. Rule on section 101.

Not a word.

We had the same exchange in the Federal Circuit and, once again, we pointed out this was 101, had been waived six ways from Sunday. Not a response telling the Federal Circuit, this isn't the case, please rule. And this is important because you're being asked to tell trial court and three courts of appeals judges that they committed reversible error for failing to address a question that nobody ever asked them.

JUSTICE BREYER: Now what do you say in response to my question to the Solicitor General?

MR. ESTRADA: Which question, Justice Breyer? I'm sorry.

JUSTICE BREYER: That they thought it was obvious, that they thought that obviously the problem here with this particular claim is that it doesn't say specifically which tests this principle is meant to apply to. So it isn't definite enough. It never occurred to anyone that if you tried to apply it to every test, it was somehow a valid patent, so they made it in the definitive context. Because for 154 years, it's been clear that you can't take a principle of nature like electricity and simply make a claim for all uses of electricity to create letters. That's their analogy.

And they thought by referring to the cases and by referring to the failure to point out definitely what the tests were this applied to, it violated 112 because otherwise, it wouldn't be a valid patent, which everyone in the patent field would know. That's at least, I think, what they're saying.

MR. ESTRADA: I think it is wrong in the facts and under law. If it was obvious all along this is an affirmative defense under section 282 of the patent code, that must be pleaded. One certainly can't be excused for

failing to plead something that, dare I say, is obvious.

But let's deal with the Morse case.

Mr. Franklin said it's the same statute at the time. Actually, that is not so. At the time Morse was decided, Section 112 and 101 were both together in section 6 of the 1836 patent act. In 1870, Congress broke that off. That's important because in Diehr, this Court considered a similar issue with respect to the novelty requirement and concluded that once Congress consciously wrote the novelty requirement out of Section 101, it was inappropriate to inject, you know, the novelty considerations into section 101.

The second answer to the Morse question, Justice Breyer, is that the test for definiteness is not is this definite in the abstract, but is it really too broad in relation to the inventive contribution as disclosed in the specifications. And the contrast here that is important to keep in mind is between Morse in 1854 and Alexander Graham Bell, claim 5 of that patent.

Just to set it up, in the Morse case, claim 8, it had been known for many years that it was possible to transmit using the electromagnetic current but nobody knew how. And in fact, this Court's ruling on page 107 says this was known by men of science everywhere. And the problem was that Morse discovered one particular way to transmit characters at a distance and tried to patent everything that

everybody might ever discover using whatever means to print at a distance.

Alexander Graham Bell is a good contrast. Claim 5. It was also known that you could use the electronic current to transmit voice. People had tried and tried and tried and, in fact, there was somebody in Germany who successfully transmitted music but no words. This is all in -- in the Court's opinion. Now, Graham Bell discovered that the key was to use continuous undulations in current. Continuous undulations, not discontinuous undulations. And had a patent claim, claim 5, which was very broad. All users of continuous undulations to transmit voice or sound. The Court said that's absolutely right, because he was not trying to claim beyond his inventive contribution to the art.

Now, Drs. Stabler and Allen in this case discovered something very important which is all of the medical tests that existed in the art as late as the 1880s -- the 1980s were wrong. People were horribly misdiagnosed. And there was a test that existed but nobody used. This is what the record was.

The test for existing homocysteine was almost never used, as Dr. Allen testified to this. There is evidence in the record. This is why we have jury trials. And what happened was this test was solely for attempting to

diagnose inherited enzyme defects. This is rare. Nobody used it. There was not a market for it.

As a result of the discovery, the medical community came around and concluded that everything they were doing was wrong and the new test combining the knowledge that it was possible to assay for homocysteine -- and by the way, the assaying means only measuring -- total homocysteine with the discovery of the correlation could be put together, as Diehr allows, to come up with a better diagnostic test. And at the time, obviously, and this is, again, in the trial testimony, no market for this. Nobody wanted to do it. Everybody was just delighted with the existing tests. And so Dr. Allen and Dr. Stabler had to set up their own lab to do it.

It was after the medical community came around that all of the lab companies became interested in doing this commercially. And I go into this level of detail because I think it is in part needed to answer the point made by the Solicitor General. In a world in which there was no commercial use for the existing prior art because it was used rarely, and a market develops solely as a result of people using the test to practice the invention, I think it's analytically incorrect to say that we're trying to monopolize the existing prior art. What has happened is commercial laboratory companies like LabCorp are selling the

test to practice our invention. It was open to them to say --

JUSTICE STEVENS: Let me just interrupt. As I understand it, the alleged infringers don't use the same novel process that you use in your assay, in other words, step 1. They do not use the step 1 in claim 13, is that correct?

MR. ESTRADA: Our -- yes and no. I think there is an ambiguity in the question, Justice Stevens, because it is true that the Abbott method --

JUSTICE STEVENS: Well, assume it's not Abbott. Just say I come up with a novel method that's not covered by the patent that I can get the assay results. And so a doctor says, would you test the blood under your unpatented, novel method and tell me what the results are?

MR. ESTRADA: All right.

JUSTICE STEVENS: And I do that and then the doctor looks at it and says I think you've got a vitamin B deficiency, has he infringed your patent?

MR. ESTRADA: If the test was not ordered for the purpose of diagnosing --

JUSTICE STEVENS: It was ordered for the purpose of letting the doctor know exactly what the assay would be. Yeah.

MR. ESTRADA: Well, unless --

JUSTICE STEVENS: He hasn't --

MR. ESTRADA: -- there was a purpose for diagnosing the deficiency, I would say no. And while we're on the subject of engaging what our arguments have been all along, we made clear in our brief, and nobody ever responded, at page 38, that claim 13 is only infringed when the assaying and the correlating steps are both performed sequentially for the purpose of diagnosing vitamin B deficiency.

JUSTICE STEVENS: If a doctor asked me to perform under my, my open method, step 1, which I do it and I give him the results and then he tells the patient, I think you've got a vitamin B deficiency, in that case, he has infringed, if I understand your argument.

MR. ESTRADA: If he did it for the purposes of trying to determine whether you had a vitamin deficiency. Now, if he did it for the purpose of trying to determine, as in the prior art, whether you had an inherited enzyme condition, that would not be infringing. And this point was addressed, obviously somewhat indirectly because it was never raised in the court of appeals, by the Federal Circuit at page 9 A and 10 A where the Federal Circuit explained the correlating step was included as a limit for the intended use of the test as a means to distinguish the intended use for this test from the prior art.

JUSTICE BREYER: You're onto something, to me, that is absolutely fundamental. You have millions of doctors and scientists and computer people who are working extremely hard to think of useful ideas and if you don't give them an incentive, they may think of less.

MR. ESTRADA: Correct.

JUSTICE BREYER: And they're all useful. At the same time, if you patent all of their ideas, including very useful mini-micro principle ideas, you will establish monopolies throughout this country beyond belief and it will be difficult for people, without paying vast amounts of money, to use their useful ideas.

So what principle do we use to separate the scientific idea which can't be patented from the process which can be? I thought that the claim was settled by Morse, Flook and Diehr. Now would it make sense -- you can answer any part of this question you want.

MR. ESTRADA: All right. Let me --

JUSTICE BREYER: Would it make sense to send this back and say, look, at least address their argument? You can answer any part of that.

MR. HUNGAR: Three answers. Number one, under the patent laws, everybody -- anybody who makes, uses or sells the invention is potentially liable as an infringer. Number two, Congress knows this and it knows that the people

who might be liable as infringers are doctors. It passed in 1996 section 287 C of the patent law that gives doctors a defense to infringement for certain things they do in their offices, not this one. So Congress is perfectly aware of all of the policy issues being raised and has chosen to give an answer only so far.

The third is it is a fundamental misconception to treat the case as though, even if the Section 101 issue is in front of the Court -- and it isn't -- whether the issue is whether Section 101 means that something is actually patentable as opposed to what Diehr said, which is, is it possibly patentable. This is subject matter patentability. Is the mouth of the funnel, not the end of the funnel, and all of the outlandish hypotheticals that we have to deal about how this could be patented don't really deal with the reality of the patent code, which is this is the intake funnel. We have doctrines of obviousness, anticipation, 112, many other things, all of which were raised at trial and the jury rejected in this case.

But the reason why there may be some superficial appeal to the outlandish hypotheticals, Justice Breyer, is because there is an effort to confuse the issue that they're trying to smuggle belatedly into the case, 101, as though it dealt with whether something is actually patentable as opposed to potentially patentable. And on the

latter question, whether something is potentially patentable, we have the extremely broad language of Section 101 coupled by this Court's cases, in Chakrabarty and Diehr, which said that what Congress intended is for anything under the sun made by man to be potentially patentable. And if there is some more precise policy issue why a particular invention ought not to be patentable, it is found in section 102, 103, 112, other parts of the patent code, on which they lost in front of the jury.

JUSTICE SCALIA: What was made by man here?

What was made by man here? I mean, if you're talking about the type of assay that your client developed, which was involved in other claims, not in 13, they might say, yeah, that was made by man. But here, what 13 involves is simply discovery of the natural principle that when one, when there is the presence of one substance in a human being, there is a deficiency of two other ones. That's just a natural principle. What's made by man about that?

MR. HUNGAR: Well, the -- we don't contend that the second step of the correlation is independently patentable even though the argument is framed as a -- argument. What we contend is patentable and what's allowed by Diehr is the inventive spark of putting together the discovery of the correlation with a way found elsewhere to measure these important bodily chemicals to produce a

diagnostic test.

JUSTICE SCALIA: It's a way found elsewhere if indeed the Federal Circuit had determined the second step, you know, step 1, do the assay, step 2, correlate. If the Federal Circuit had said, oh, that requires your using a scale to see how much of one there is and how little of the other, but this Federal Circuit says, all correlate means is be aware of the fact that when one substance is high, the other two are going to be low. That's all it means.

MR. HUNGAR: Well, that's unfair to the Federal Circuit on two points. Number one, it was very clear to the Federal Circuit, and in fact I think they said that, I can't put my hand on the page, where they said, there is no issue here about step number one. All that people are fighting about is the correlating step and what it means.

And the problem that LabCorp had in the Federal Circuit with respect to the correlating step, which is a question they tried to bring up and was cert denied, is that they proposed in the district court the definition that was used by the Federal Circuit, which is a mutual or reciprocal relationship between an elevated level and the vitamin. And so having proposed that, it actually makes sense as a diagnostic test, as the Federal Circuit pointed out with the example of the pregnancy test.

Now, Justice Scalia, you asked a question

earlier --

JUSTICE SCALIA: No, please don't get off it -- because this is my biggest problem with the case. I agree that what you've said is simply a statement of the natural phenomenon, that when the one substance is high, the other two are low. And simply to be aware of that natural phenomenon is all that correlation consists of.

MR. HUNGAR: Well, it is true but is not necessarily the case that being aware of a natural phenomenon or of a correlation leads you inevitably to an inventive diagnostic test. There is a correlation between being told and between height and weight. If I tell you that somebody's coming to visit you who is 250 pounds, that person is probably not a five year-old. But that gets me nowhere in terms of turning that into useful knowledge that would be patentable.

JUSTICE STEVENS: But you agree with me, do you not, that step 2 by itself would not be patentable?

MR. HUNGAR: I do agree with that, Justice Stevens.

JUSTICE STEVENS: Your point is that even though step 2 is performed as the second step of step 1 which is also not patentable, you get together for the patent?

MR. HUNGAR: That's true. And if you look at

the Diehr case, it's a perfect example because Diehr had more steps but it was absolutely true in Diehr that every single step, including the mathematical equation, was part of the prior art. And this Court said that's potentially patentable because you have found a way to put all these disparate things together in a way that makes them potentially useful.

JUSTICE BREYER: But does that fall within it? I mean, I can't resist pointing, as one of these beliefs did, the phrase that anything under the sun that is made by man comes from a committee report that said something different. It said a person may have invented a machine or a manufacture, which may include anything under the sun that is made by man.

So referring to that doesn't help solve the problem where we're not talking about a machine or a manufacture. Rather we are talking about what has to be done in order to make an abstract idea fall within the patent act. Now, sometimes you can make that happen by connecting it with some physical things in the world and sometimes you can't.

MR. HUNGAR: But Justice Breyer --

JUSTICE BREYER: And if you have a clear statement other than Diehr, Flook, Morse, which draws that line properly, let me know.

MR. HUNGAR: I think the telephone cases, Bell and Diehr, are cases that absolutely show that under this Court's cases, this is patentable subject matter. Again, we're talking about the mouth of the funnel, not the end of the funnel.

But let me point something else, Justice Breyer, which is it came from a committee report that has already been incorporated in this Court's cases in Chakrabarty and in Diehr as exemplary of Congress' determination to have the mouth of the funnel be very wide. And if there are problems with something being ultimately patentable, they are because there is some other requirement of the patent law that -- that -- that should be looked at.

One of the other points on the question that Justice Scalia asked, because I think it is important on whether this question is before the Court, is that the rules of this Court, rule 14-1-F mandate that the petition shall contain, quote, the status involved in the case set out verbatim. And you can pick up the cert petition and indeed there is an appendix which is at the very last page of the petition, and you can look at it and it says, pertinent statutory provisions. There are two statutes, Section 112 and section 271. You can pick up their blue brief and do the same with the back flap, and we would have the fishes and the loaves.

Now they have three statutes, 101, 112 and 271. There is no way to construe their question 3 as having been intended all along to encompass a very separate affirmative defense that they never put in front of the trial court or the Federal Circuit.

JUSTICE STEVENS: Would the case be different if they quoted Section 101 in their appendix?

MR. HUNGAR: Yes, I think it would be different, Justice Stevens, because then their argument that this was encompassed within one of the questions in the petition might have some surface plausibility. But it doesn't.

Let me just go back and link that point with another aspect of our legal system, which is you see cases of forfeiture and waiver all the time. This term in Unitherm and in Arbaugh, you have already said twice that parties should be held responsible for their procedural defaults. You do that in other areas of the law.

And the one that came to mind, to my mind as I was thinking about this case, Justice Stevens, is going all the way back to Wainwright versus Sykes, because you have cases every year involving habeas corpus, where Wainwright versus Sykes says we have to be careful about sandbagging, and we're going to presume that an indigent defendant on trial for his life in a rural county someplace with a lawyer

two years out of law school, who can't find the courthouse, consciously chose to save the federal claims so that he could assert later, have it in his back pocket: We're going to have a rule of forfeiture for sandbagging.

Empirically, one may well wonder whether that is empirically likely to be true in a great number of cases. But we don't have to wonder in this case because every well advised corporate defendant, if I am their lawyer, I will advise them to hold this in the back pocket and to have a second trip to the trial court and the court of appeals because in the rules in affirmative defense, rule 8 says you have to plead it and the statute says you have to prove it. And it went all the way up the ladder.

And if you tell them that they get to start all over again, what you will have is every well advised corporate defendant will be advised by counsel, like me and by Mr. Franklin, that the way to do is to tire the inventor out, have a trial and then we can start all over again. And that's no way to run a legal system, especially when they're coming with the most important questions of patent law to this Court with incredibly far-reaching implications and the best that they can say to the Court about why you shouldn't worry about the consequences is, as they say in the closing pages of the reply brief, rule for us and every other case will have to be considered on its own merits. Which I guess

is true as far as it goes but it's about as helpful as telling the Patent Office and the lower courts that life is a fountain. And you know, this Court does not sit to issue --

JUSTICE SCALIA: You mean life isn't a fountain?

(Laughter.)

MR. HUNGAR: I didn't say it wasn't. I just said that the expression of that thought is not helpful. And insofar as this Court sits to advise the lower courts and the government and the patents office and the investing community who could swing billions of dollars on the basis of an issue that was never litigated in the lower courts, I frankly submit, Justice Scalia, that it would be irresponsible for the Court to reach out and deal with a question for which there was never an adequate factual predicate.

JUSTICE STEVENS: And Wainwright against Sykes was even decided before AEDPA was passed, too.

MR. HUNGAR: Exactly. And Congress actually implemented that in AEDPA. And so my basic point, Justice Stevens, is if that the legal system takes the procedural regularity of our courts seriously enough to enforce them in what would seem to some people to be pretty compelling circumstances of life and death, there is little claim on

the legal system for a well heeled corporate defendant who has been adjudged to be a willful infringer by a jury to come to this Court and asked to be put in the starting gate again. There is no way that -- again, that is no way to deal with the legal system.

I have nothing further, Justice Stevens.

JUSTICE STEVENS: Thank you, Mr. Estrada.

Mr. Franklin, I think you have about four and a half minutes left.

REBUTTAL ARGUMENT BY JONATHAN S. FRANKLIN

ON BEHALF OF THE PETITIONER

MR. FRANKLIN: Hopefully I won't, I won't have to use all that.

Just a few points, Your Honors. There was a suggestion made that it matters what purpose these tests were undertaken for. That is not true. We had argued extensively that it did matter, that in fact the doctors were using this for not detecting vitamin deficiencies but for detecting heart disease. That was not -- we were not successful on that. What the court of appeals said was any doctor on pain of malpractice will necessarily perform the correlating every time that doctor looks at a test result. So it doesn't matter why the doctor does that.

Second, Morse was clearly a case decided under what is now Section 112. I think Mr. Hungar admitted that.

The language of the case makes that clear. It quotes the relevant statute, and all of this is in our reply brief, and it concludes that the patent in that case was overbroad because it didn't, it contravened what is now Section 112 and that is how we argued --

JUSTICE STEVENS: Weren't 112 and 101 combined at that time?

MR. FRANKLIN: They were.

JUSTICE STEVENS: Do you disagree with that?

MR. FRANKLIN: No, I don't. He is correct on that. But look at the case and how it was decided. It was decided on the basis of what is now Section 112. We have cited numerous cases in the lower courts that have interpreted it that way. And I believe Mr. Hungar admitted that too.

JUSTICE STEVENS: I don't want to take up your time on rebuttal but I have to ask you, do you have an explanation for not quoting section 101 in your papers?

MR. FRANKLIN: I think the explanation is that we cited all of the cases -- for example, Mackay Radio is a case we cited that doesn't itself cite 101. The Court itself never cited 101 in these cases until 1972. It was a judicially created exception for laws of nature and natural phenomena. And of course to the extent it is applicable here, it is applicable either on its own, but also in

connection with and as a natural predicate to the 112 inquiry. And there I think the analogy of Morse is quite striking. And what -- in Morse, the Court said that he could not monopolize all devices and processes used to transmit the characters at a distance through the natural phenomenon of electromagnetism.

Here what these patent cases are seeking to do is to monopolize all homocysteine tests that are used to, as they say, detect vitamin deficiencies through the natural correlation that they recite. Morse couldn't do that because it wasn't limited to the one device that he actually invented. Here they cannot do it because it's not limited to the one homocysteine assay that they in fact invented, that we use and that we pay royalties on every time we use.

Finally, I think that the primary gatekeepers here on these kinds of things is the Patent & Trademark Office. I think they're trying their best, but what I heard from their representative today is that they're not prepared to do anything about these kinds of patents unless this Court gives them further guidance. We are only asking that the Court give them further guidance on this patent and to say that a patent that claims nothing more than a natural correlation preceded by the inherent and generic step of measuring the input for that correlation is invalid and the judgment that is based upon it should also be reversed.

Thank you, Your Honors.

JUSTICE STEVENS: Thank you. The case is submitted.

(Whereupon, at 12:11 p.m., the case in the above-titled matter was submitted.)